

CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)

Applicant(s):

Docket No.

31140B

Serial No.
10/051,662Filing Date
January 18, 2002Examiner
R. CookGroup Art Unit
1614

Invention:

PREVENTION OF OVARIAN CANCER BY ADMINISTRATION OF A VITAMIN D COMPOUND

I hereby certify that the following correspondence:

1449 Form (with listed references)*(Identify type of correspondence)*

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

March 31, 2004*(Date)**(Typed or Printed Name of Person Mailing Correspondence)**(Signature of Person Mailing Correspondence)*EL395644806US*("Express Mail" Mailing Label Number)*

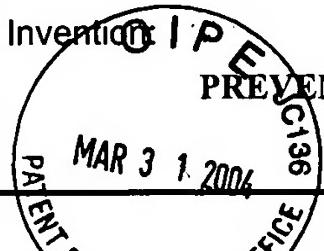
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1614**PREVENTION OF OVARIAN CANCER BY ADMINISTRATION OF A VITAMIN D COMPOUND**

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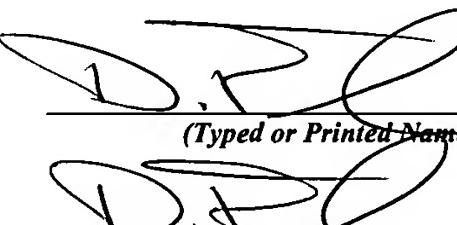
Supplemental Information Disclosure Statement

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Serial No.: 10/051,662

Our File No. 31140-B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Rodriguez et al.)
Serial No.: 10/051662) Examiner: R. Cook
Filed: January 18, 2002) Group Art Unit: 1614
For: Prevention of Ovarian Cancer by)
 Administration of a Vitamin D Compound)
)

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

To: Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR §1.97(c), applicants submit this Supplemental Information Disclosure Statement, submitting the art listed in the attached PTO Form 1449.

This Supplemental Information Disclosure Statement includes the following three categories of references: (1) two U.S. Patents issued in the name of Applicants, namely U.S. Patent Nos. 6,407,082 and 6,444,658; (2) Neer et al. U.S. Patent No. 4,833,125 (“the Neer patent”), as well as documents from Applicants’ related PCT application, PCT/US98/11737; and (3) the full Need reference (applicants previously provided a copy of the full reference with their amendment dated February 5, 2004, but with an Information Disclosure Statement).

A. The Neer Patent

The International Preliminary Examination Report for Applicants' PCT application PCT/US98/11737 cites the Neer patent. A copy of the Report is included herewith. The report identifies col. 7, lines 16-19 as pertinent to one claim in the PCT application. The cited portion of the Neer patent reads:

A typical pharmaceutical mixed composition of the invention would contain PTHF in combination with a hydroxylated vitamin D compound or calcium in a form suitable for use as a dietary calcium supplement.

The Neer patent was cited only against claim 25 in the pending PCT application. The other claims were found to have novelty and inventive step over the references cited. (*See International Preliminary Examination Report, V.1.*).

Claim 25 of application PCT/US98/11737 reads as follows:

25. A pharmaceutical composition for inhibiting the conversion of non-neoplastic ovarian epithelial cells to neoplastic cells comprising a **Vitamin D compound** and a **hormone product**.

(*See* PCT/US98/11737 submitted herewith). Thus, claim 25 was directed to a combination of a Vitamin D compound and a hormone product. The International examining entity cited the Neer reference as showing that claim 25 lacked novelty. (*See* International Preliminary Examination Report at V.1.). Neer combines a parathyroid hormone, PTHF, with either Vitamin D or calcium.

However, the International Application also included claims directed to the combination of Vitamin D and a progestin product, specifically claims 26-34. Claim 26 is exemplary:

26. The pharmaceutical composition of claim 25 wherein said hormone is a **progestin product**.

With respect to the claims directed to the combination of Vitamin D and a progestin product, the International examining entity found both novelty and inventive step. (*See* International Preliminary Examination Report at V.1.). Neer does not disclose or suggest any use of a progestin product.

In the pending U.S. Application Serial No. 10/051,662 at issue here, claims 35 and 45 were the only two claims that broadly recited “a hormone product.” However, those claims are now amended to be more narrowly drawn to “a progestin product.”

The Supplemental Information Disclosure Statement also includes the Initial International Search Report in connection with the same application PCT/US98/11737.

B. The Full Need Reference

In the August 7, 2003 Office Action, the Examiner brought to the Applicants' attention the abstract of the Need et al. reference. Applicants submitted a copy of the full Need reference with their prior amendment of February 9, 2004. As explained in the Applicants' amendment filed February 9, 2004, the Need reference does not teach or provide any motivation to make: (1) a single unit dosage of Vitamin D and progestin; (2) a contraceptively effective regimen having both Vitamin D and a progestin; or (3) any dosages for administration to post-menopausal women in specific dosages different from what Need used.

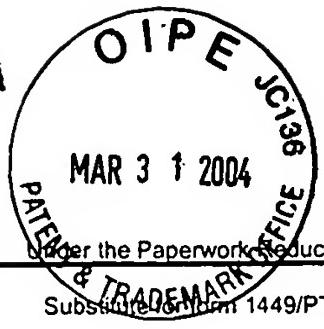
Please charge the fee required by 37 CFR §1.97(c)(2) and §1.17(p), and any additional fees, to Deposit Account No. 18-1942.

Respectfully submitted,



Raymond N. Nimrod
ROPER & QUIGG
Reg. No. 31,987
200 South Michigan Avenue
Suite 1000
Chicago, Illinois 60604
Tel (312) 408-0855

March 31, 2004



MAR 3 1 2004

Substation Form 1449/PTO

**SUPPLEMENTAL
INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

(Use as many sheets as necessary)

Sheet 1

of 2

Complete if Known

Complete if known.

10/051 662

Complete if Known

Application Number	10/051,662
Filing Date	01/18/02
First Named Inventor	RODRIGUEZ
Art Unit	1614
Examiner Name	R. Cook
Attorney Docket Number	31140B

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U. S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

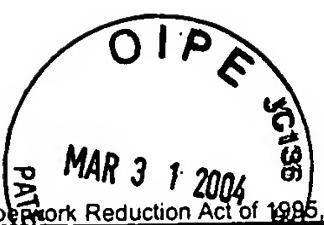
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	E1	PCT Int'l App.	12-17-1998	Rodriguez et al		
		WO98/56389				
	E2	Int'l Prel. Ex. Rpt.	09-09-1999	Rodriguez et al		
		PCT/US98/11737				
	E3	Int'l Search Rpt.	09-09-1999	Rodriguez et al		
		PCT/US98/11737				

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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PTO/SB/08B (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Complete if Known

Substitute for form 1449 PTO

**SUPPLEMENTAL
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STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

2

of

2

Application Number	10/051,662
Filing Date	01/18/02
First Named Inventor	RODRIGUEZ
Art Unit	1614
Examiner Name	R. Cook
Attorney Docket Number	31140B

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	F1	Need et al., "Comparison of calcium, calcitrol, ovarian hormones and nandrolone in the treatment of osteoporosis." Maturitas 8:275-280 (1986).	

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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